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IP

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/785,532	01/17/97	GRAY J	2500.124US2

020227 HM12/0130
MAJESTIC PARSONS SIEBERT & HSUE
SUITE 1100
FOUR EMBARCADERO CENTER
SAN FRANCISCO CA 94111-4106

EXAMINER	
DAVIS,M	
ART UNIT	PAPER NUMBER
1642	24

DATE MAILED: 01/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/785,532	Applicant(s) Gray et al
	Examiner Minh-Tam Davis	Group Art Unit 1642

☒ Responsive to communication(s) filed on *Nov 21, 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-63* is/are pending in the application.

Of the above, claim(s) *1-25, 29-36, 38-55, and 57-60* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *26-28, 37, 56, and 61-63* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

The request filed on 11/21/2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No: 08/785532 is acceptable and a CPA has been established. An action on the CPA follows.

Since species SEQ ID NO:9 has been elected, claims 26-28, 37, 56, 61-63 are being examined. Claims 29-36, 38-40, 48-55, 57-60, drawn to non-elected species, are withdrawn from consideration.

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH, NEW REJECTION

Claims 26-28, 37, 56, 61-63 are indefinite, because claim 26 lacks a necessary step to correlate the result with the preamble of claim 26.

REJECTION UNDER 35 USC 102

Rejection under 35 USC 102 of claims 26, 56 and 61-63 pertaining to anticipation by Morris et al remains for reasons already of record in paper No. 14.

Applicant argues as follows:

Every element of the rejected claims is not identically shown in Morris et al. Morris et al do not teach a step of determining increased copy number of nucleic acid sequences at chromosomal region 20q13.2. Morris et al do not even mention chromosome 20.

It is unclear what portion of the probe taught by Morris et al is 88% similar to SEQ ID NO: 9. Thus it is unclear that the probe of Morris et al would inherently hybridize to SEQ ID NO: 9 from 20q13.2. Furthermore the present claims are not directed to a probe, but to a method.

Applicant's arguments set forth in paper No.16 have been considered but are not deemed to be persuasive for the following reasons:

A portion of the probe taught by Morris et al (from nucleotide number 86498 to 86778) is 88% similar to the SEQ ID NO:9 from nucleotide number 7427 to 7708, as shown by MPSRCH sequence search, from the copy entitled US-08-731-499-9-05, rge. A copy of said search was sent to applicant on the Office action on September 7, 1997. An extra copy of said search is enclosed in the instant Office Action.

The method taught by Morris et al is the same as the claimed method, i.e. hybridization of a probe to a sample. The probe taught by Morris et al would inherently hybridize under stringent conditions to SEQ ID NO: 9 from 20q13.2. Although Morris et al do not mention chromosome 20, the cancerous sample taught by Morris et al would inherently contain chromosome 20. Thus hybridization to SEQ ID NO:9 on chromosome 20 by the probe taught by Morris et al would inherently occur, because the probe taught by Morris et al is 88% similar to SEQ ID NO:9. Furthermore, although Morris et al do not mention determining an increased copy number of

nucleic acid sequences at chromosomal region 20q13.2, the method taught by Morris et al would inherently show an increased copy number of nucleic acid sequences at chromosomal region 20q13.2, because the probe by Morris et al would inherently hybridize to an increased copy number of SEQ ID NO:9 present on region 20q13.2.

REJECTION UNDER 35 USC 112 FIRST PARAGRAPH, ENABLEMENT

Claims 26, 28, 37, 56, 61-63 remain rejected under 35 USC 112, first paragraph as the specification fails to provide an enabled disclosure of a method for screening any neoplastic cells, as set forth in the previous office action of paper No. 14.

Applicant argues as follows:

One of skill in the art can test any biological sample and determine if the sample contains cells having an increased copy number of nucleic acid sequences at region 20q13.2, because applicant discloses the probes, and assays, such as in situ hybridization or souther blots.

Applicant's arguments set forth in paper No. 16 have been considered but are not deemed to be persuasive for the following reasons:

Although of skill in the art can test any biological sample and determine if the sample contains cells having an increased copy number of nucleic acid sequences at region 20q13.2, the increased copy number of SEQ ID NO:9 does not mean that any cancer, including ovarian, bladder and colorectal tumor is present. The claimed sequence SEQ ID NO:9 which consists only of 2kb is not necessary within the area associated with any type of cancer, including ovarian,

bladder and colorectal tumor. Yet applicant has not shown that SEQ ID NO:9 region is associated any type of cancer, including ovarian, bladder and colorectal tumor. Furthermore, the art teaches the contrary, i.e. not all types of cancer are neccessarily associated with abnormality of the chromosome 20q13.2.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, NEW MATTER, NEW REJECTION

Claims 26-28, 37, 56, 61-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 26-28, 37, 56, 61-63 are drawn to a method for detecting the "absence" of cancer in a sample "having" an increased copy number of nucleic acid sequences at chromosome region 20q13.2.

The specification discloses that an increased copy number of nucleic acid sequences at chromosome region 20q13.2 is an indication of the presence of breat cancer (p.49-51). The specification does not contemplate nor discloses a method for detecting the absence of cancer in a sample having an increased copy number of nucleic acid sequences at chromosome region 20q13.2.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION, NEW REJECTION

The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

The claims 26, 37 are drawn to a method of detecting the presence or absence of neoplastic cells comprising hybridizing under stringent conditions to a probe which hybridizes to SEQ IS NO:9, wherein the probe "comprises" SEQ ID NO:9.

The specification discloses a genomic sequence of SEQ ID NO:9, which includes roughly 2kb of a promoter region (p.21, lines 14-15). Absent evidence to the contrary, SEQ ID NO:9 elected for examination is deemed to be an incomplete DNA sequence. Because the DNA sequence that correspond to SEQ ID NO: 9 mentioned in the claims is not full-length, a sequence prepared from undefined parts of a DNA sequence will not comprise the entire coding region of any particular gene. The claims, as written, however, encompass a method of detecting the presence or absence of neoplastic cells, comprising hybridizing under stringent conditions to a probe, which comprises polynucleotides with substantial variation in length and also in nucleotide composition. The broadly claimed genus encompasses genes incorporating only portions of the disclosed sequence.

The instant disclosure of a single species of nucleic acid does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-

length genes. The findings of *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412) are clearly relevant to the instant rejection. The court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". The specification discloses only a single common structural feature, i.e. SEQ ID NO:9, which are shared by members of the claimed genus. Since the claimed genus encompasses genes yet to be discovered, the disclosed structural feature does not constitute the claimed genus. Therefore, the disclosure of SEQ ID NO:9 does not provide an adequate description of the claimed genus. Only an isolated DNA molecule consisting of SEQ ID NO: 9, but not the full breadth of the claims meet the written description provisions of 35 USC 112, first paragraph.

One of skill in the art would reasonably conclude that applicant was not in possession of a method of detecting the presence or absence of neoplastic cells, comprising hybridizing under stringent conditions to a probe, which comprises the genus DNAs, wherein said genus DNAs comprises SEQ ID NO:9.

REJECTION UNDER 35 USC 112 FIRST PARAGRAPH, ENABLEMENT, NEW REJECTION

Claims 26-28, 37, 56, 61-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 26-28, 37, 56, 61-63 are drawn to a method for detecting the "absence" of cancer in a sample "having" an increased copy number of nucleic acid sequences at chromosome region 20q13.2.

The specification discloses that an increased copy number of nucleic acid sequences at chromosome region 20q13.2 is an indication of the presence of breat cancer (p.49-51).

It is not clear how one could determine the absence of cancer in a sample having an increased copy number of nucleic acid sequences at chromosome region 20q13.2, wherein an increased copy number of nucleic acid sequences at chromosome region 20q13.2 is an indication of the presence of cancer. In view of the above, it would have been undue experimentation for one of skill in the art to practice the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The

examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wesnesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

January 21, 2001